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EXAMINER	
RALIS, STEPHEN J	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/684,124	**Applicant(s)** BURBANK ET AL.	
	Examiner Stephen J. Ralis	**Art Unit** 3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-38,45-49,53-55,59-64 and 66-110* is/are pending in the application.

4a) Of the above claim(s) *102-106* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-38,45-49,53-55,59-64,66-101 and 107-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Applicant is respectfully requested to provide a location within the disclosure to support any further amendments to the claims due to when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should specifically point out the support for any amendments made to the disclosure.").

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 March 2008 has been entered.

Response to Amendment/Arguments

4. Applicant's arguments filed 24 March 2008 with respect to the 35 U.S.C. 112, first paragraph, new matter issue have been deemed persuasive and the examiner respectfully withdraws that rejection.

5. Applicant's arguments filed 24 March 2008 have been fully considered but they are not persuasive as set forth below:

Priority

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

7. However, the limitations of at least "at least one of the bodies being ultrasonically detectable and with at least one of the other bodies being formed of cross-linked bioabsorbable material and having a radiographically detectable …" in claims 35-38, 45-49, 53-55 and 59-61 does not have support in the parent application, 09/241,936 now U.S. Patent No. 6,161,034, since based on the specification and drawings, the only components that are disclosed are a radiographically detectable marker comprising a substance or objects(s) of a different color. There is no support for a plurality of elements with one having ultrasonically detectability and the other/another (exclusive thereof) having radiographically detectability.

Similarly, the limitations of claims 59-64 and 107 do not have support in the parent application, 09/241,936 now U.S. Patent No. 6,161,034, since based on the specification and drawings, the only components that are disclosed are a radiographically detectable marker comprising a substance or objects(s) of a different color. There is no disclosure of a radiographically detectable marker being imbedded therein within the marker body as well as the marker having a pair if free ends and being in the shape of a Greek letter gamma.

Accordingly, at least claims 35-38, 45-49, 53-55, 59-64 and 107 are not entitled to the benefit of the initial parent prior application, however, do get priority based on child application, 09/343,975 now U.S. Patent No. 6,347,241, derived form the above mentioned parent application.

Claim Objections

8. Claims 62 and 87 objected to because of the following informalities:

Claim 62, line 3: “a plurality of remotely detectable solid ultrasonically detectable body” should read –a plurality of remotely detectable solid ultrasonically detectable bodies–.

Claim 87, lines 1-2: " a plurality remotely detectable marker bodies” should read –a plurality of remotely detectable marker bodies–; line: “a inner lumen” should read –an inner lumen–.

The above notes are exemplary with respect to all of the claim objections present in the instant case. So as to avoid an antecedent basis issues and to provide clear and consistent language throughout the claims, all claims must be carefully reviewed and appropriate corrections should be made in response to this objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 35-38, 45-49, 53-55, 59-64, 66-101 and 107-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 62 recite "A marker… comprising: a plurality of separate preshaped solid remotely detectable bodies...". It is unclear to the examiner how a single marker can have a plurality of detectable bodies since a plurality of separate preshaped bodies would not be a singular entity. Further clarification is required.

Claim 45 and 59 recite "a system/device for delivery of a plurality of marker bodies…", "a plurality of separate solid marker bodies.." and "at least one marker body… and another marker body". It is unclear to the examiner the structural relationship between the "a plurality of marker bodies" and "a plurality of separate solid marker bodies" in addition to whether the "at least one marker body… and another marker body" are part of the "a plurality of marker bodies" or "a plurality of separate solid marker bodies" or even independent elements. Further clarification is required.

Similarly, claim 53 recites "a plurality of marker bodies…", "a plurality of separate solid marker bodies.." and "at least one body… and with another body". It is unclear to the examiner the structural relationship between the "a plurality of marker bodies" and "a plurality of separate solid marker bodies" in addition to whether the "at least one body… and with another body" are part of the "a plurality of marker bodies" or "a plurality of separate solid marker bodies" or even independent elements. Furthermore, there is only a recitation to the plunger moving "the plurality of marker bodies" not any other bodies. Further clarification is required.

Claim 66 and 107 recite similar limitations to “A system for delivering a marker body comprising: a delivery cannula having a inner lumen…. configured to urge a marker body out of a discharge port…”. In addition, claim 66 recites “a plurality of marker bodies with at least one solid preshaped marker body…; and a plunger... within the inner lumen… configured to urge the plurality of marker bodies into engagement with the ramp and slidably move the plurality of marker bodies up the ramp and out of…” ..”. It is unclear to the examiner how a single marker can have a plurality of detectable bodies since a plurality of separate preshaped bodies would not be a singular entity. Furthermore, it is unclear if the apparatus/device is configured to urge a single marker element or a plurality of marker elements. Further clarification is required.

Claim 87 recites similarly limitations as noted above with respect to “a plurality of remotely detectable marker bodies” (twice), "a plurality of marker bodies” and ““at least one marker body”. It is unclear to the examiner the structural relationship between the “a plurality of marker bodies” and “a plurality of remotely detectable marker bodies” in addition to whether the “at least one marker body” is part of the “a plurality of marker bodies” or “a plurality of remotely detectable marker bodies” or even independent elements. Furthermore, there is only a recitation to the plunger moving “the plurality of marker bodies” not any other bodies. Further clarification is required.

In general, the claims are replete with such 35 U.S.C. 112, second paragraph issues. The above notes are exemplary with respect to all of the 35 U.S.C. 112, second paragraph rejections present in the instant case, all claims must be carefully reviewed and appropriate corrections should be made in response to this rejection.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 35-38, 45-49, 53-55, 109 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (U.S. Patent No. 6,270,464) in view of Yamamoto (U.S. Patent No. 4,847,049), as evidenced by Ronan et al. (U.S. Patent No. 5,820,918), and further in view of Foerster et al. (U.S. Patent No. 6,228,055).

Fulton, III et al. disclose a biopsy site marker (34) from a dehydrated collagen plug (dehydrated being solid and the plug would inherently be fabricated to a predetermined size to fit within the barrel 30 in its pre-delivered state) so that the marker swells and softens in its post-delivery state following delivery from delivery device (32) (see (1) column 5, lines 3-21, (2) column 6, lines 47-50, and (3) Figure 5). *Fulton, III et al. also disclose the requirement of the biopsy element (34) being placed within the biopsied open region (26) and substantially fills the biopsied open region (column 5, lines 3-21; column 6, lines 42-56)*. In addition to its visual detectability via a coloring agent (column 3, lines 53-54), the marker is also ultrasonically and radiographically detectable (column 3, lines 56-59). Furthermore, Fulton, III et al. note in column 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material.

Fulton, III et al. disclose all of the limitations of the claimed invention, as previously set forth, except for at least one of the bodies being formed of a cross-linked bioabsorbable material and having a radiographically detectable metallic ion bound to the cross-linked bioabsorbable material and the cross-linked material being subject to ultraviolet radiation to strengthen the bond of the metallic ion to the collagen.

However, binding metallic ions to collagens in medical devices used in contact with bodily fluids and tissues is well known in the art to protect against bacterial and fungal attack. Yamamoto, for example, discloses contacting a renatured, cross-linked collagen with silver ion-containing solution with a PH from 4.0-9.0 to cause silver ions to be chelated to functional groups in the renatured collagen. The silver-chelated collagen is then exposed to UV radiation at a 210-310 nm wavelength for 5-15 minutes (column 4, lines 23-24) to strengthen the binding of the silver ions to the renatured collagen (column 2, lines 7-19 and 60-68). Yamamoto further teaches the use of renatured collagen instead of naturally occurring collagen to provide a collagen material that is less antigenic (column 1, lines 41-46). Ronan et al. teach that in addition to the silver ions having effective antiseptic characteristics, that the heavy metal of silver has inherent radiopaque characteristics.

Similarly, Fulton, III et al. disclose all of the limitations of the claimed invention, as previously set forth, except for calling for a plurality of separate ultrasonically-detectable and radiographically-detectable bodies; and a delivery cannula with inner lumen and plunger to press against the marker bodies to discharge them from the cannula's discharge port.

However, delivering a plurality of separate detectable bodies is known in the art. Foerster et al., for example, disclose, in Figures 12-15, a cannula (tube 54; column 4, lines 31-35) that is adapted to eject a plurality of biopsy markers (12b-12e) to a desired biopsy site via an ejector rod (column 10, lines 5-11). Foerster et al. also disclose the use of a gamma-shaped radiopaque element having a pair of extensions with free-ends to outwardly extend, thereby sufficiently to anchoring themselves to the target tissue (column 11, lines 27-32; see Figures 12-14). Such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). Foerster et al. further teach a plurality of small beads (12i) of radiodense material could be deployed as marker elements in the biopsy cavity to serve as a guide during the extraction procedure and to denote the location of the previous biopsy for reference purposes (column 13, lines 16-29).

In addition, delivery cannulas with such features are known in the art. Foerster et al., for example, disclose in Figures 12-15 a delivery cannula for implanting biopsy site markers that ejects biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. Such a feature utilizes compressive forces rather than tensile forces for delivery (column 10, lines 5-12). Moreover, as noted in column 10, lines 5-11 and column 13, lines 16-29, the device can eject multiple markers individually in series.

In view of Yamamoto, as evidenced by Ronan et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to bind a radiographically detectable metallic ion to the bioabsorbable material of Fulton, III et al. to cause silver ions to be chelated to functional groups in the collagen, thus further protecting against bacterial and fungal attack in addition to the inherent radiopaque characteristics of the silver ions.

Similarly, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify Fulton, III et al. to provide a multiple detectable bodies in lieu of a single body in order to enable secure implanting of an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites. In addition, It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify Fulton, III et al. to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus cavity to serve as a guide during the extraction procedure and to denote the location of the previous biopsy for reference purposes. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a marker delivery cannula and plunger in lieu of the marker delivery device of Fulton, III et al. to eject biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window, thus eliminating a procedural step and saving time.

With respect to the limitation of the marker being also ultrasonically and radiographically detectable, Fulton, III et al. disclose, as noted above, a single marker being ultrasonically and radiographically detectable (column 3, lines 56-59). Fulton, III et al. also disclose that the change in the bioabsorbable element can occur via one of several ways (column 3, lines 45-50). Fulton, III et al. further disclose that the invention may employ one or more of these techniques or measures. For instance, *Fulton, III et al. disclose "the palpable marker may be inserted into the suspicious area of the breast under mammographic or ultrasonic guidance"* (column 2, lines 47-50; column 3, lines 15-18). The examiner respectfully disagrees that the radiographic detection and ultrasonic detection are only mutually exclusive. Fulton, III. et al. clearly disclose a single element that has mammographic or ultrasonic guidance functionality, thereby inherently having the ability to function with both radiographical and ultrasonic equipment. In addition, Fulton, III et al. explicitly disclose a single bioabsorbable element (34) that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced (column 3, lines 45-59). There is no disclosure that the single bioabsorbable element can only be enhanced by a single enhancement. Since Fulton, III et al. explicitly disclose that one or more techniques may be employed for measurement, and visual detectability, radiographic detectability, and ultrasonic detectability being separate measurements of the element, the bioabsorbable element may inherently employ both radiographic detectability and ultrasonic detectability. Furthermore, since Fulton, III et al. disclose a single bioabsorbable element having visual, radiographical and ultrasonic detectability and in view of the Foerster et al. teaching of a plurality of separate markers, Fulton, III et al. in view of Foerster et al. would have a plurality of separate markers that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced, thereby meeting “with at least one marker body which is ultrasonically detectable and at least one other marker body which is radiographically detectable” given its broadest reasonable interpretation.

Furthermore, to the degree it can be argued that the combination does not teach a plurality of markers which has one being ultrasonically detectable and another being radiographically detected, to provide a plurality of markers which has one which being ultrasonically detectable and another being radiographically detected would have been a mere engineering expediency as Fulton, III et al. clearly teach the use of a single marker being ultrasonically and radiographically detectable (column 3, lines 56-59) as well as a single bioabsorbable element (34) that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced (column 3, lines 13-18) and

Foerster et al. teach the use of a plurality of separate markers being used for marking a biopsy site in a single application.

With respect to the limitation of the plurality of separate preshaped solid bodies being collectively configured to at least partially fill the biopsy cavity site, Fulton, III et al. explicitly disclose the requirement and concern of the biopsy element (34) being placed within the biopsied open region (26) *and substantially filling the biopsied open region* (column 5, lines 3-21; column 6, lines 42-56). Foerster et al. is cited for the teaching, in Figures 12-15, of a cannula (tube 54; column 4, lines 31-35) that is adapted to eject a plurality of biopsy markers (12b-12e) to a desired biopsy site via an ejector rod (column 10, lines 5-11). In addition, Foerster et al. teach such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). Foerster et al. further teach a plurality of small beads (12i) of radiodense material could be deployed as marker elements in the biopsy cavity to serve as a guide during the extraction procedure and to denote the location of the previous biopsy for reference purposes (column 13, lines 16-29). Foerster et al. does not teach away from the use of the device or the plurality of separate preshaped solid bodies being collectively configured to at least partially fill the biopsy cavity site only a preference to use the device at multiple locations. Therefore since Fulton, III et al. explicitly teach the requirement and concern of the biopsy element (34) being placed within the biopsied open region (26) *and substantially filling the biopsied open region* and Foerster et al. teach the use of plurality of separate preshaped solid bodies within a cannula and delivery of such without reloading, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the filling substantially the entire biopsy region with one element of Fulton, III et al. with the plurality of elements of Foerster et al. as noted above.

Regarding claim 35, the cited prior art does not expressly disclose the body's ability to remain solid at 40º C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40º C in the previously described apparatus to ensure the marker remained intact after implantation. Regarding claims 46-49, although the cited prior ad does not disclose the specific Bloom rating of the body, the body of the cited prior art is nonetheless within the claimed Bloom rating range to achieve implantation (i.e., the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation).

15. Claims 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (U.S. Patent No. 6,270,464) in view of Foerster et al. (U.S. Patent No. 6,228,055).

Fulton, III et al. disclose a biopsy site marker (34) from a dehydrated collagen (dehydrated being solid) so that the marker swells and softens in its post-delivery state following delivery from delivery device (32) (see (1) column 5, lines 3-21, (2) column 6, lines 47-50, and (3) Figure 5). In addition to its visual detectability via a coloring agent (column 3, lines 53-54), the marker is also ultrasonically and radiographically detectable (column 3, lines 56-59). Furthermore, Fulton, III et al. note in column 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material.

Fulton, III et al. disclose all of the limitations of the claimed invention, as previously set forth, except for a delivery cannula with inner lumen and plunger to press against the marker bodies to discharge them from the cannula's discharge port.

However, delivery cannulas with such features are known in the art. Foerster et al., for example, disclose in Figures 12-15 a delivery cannula for implanting biopsy site markers that ejects biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. Such a feature utilizes compressive forces rather than tensile forces for delivery (column 10, lines 5-12). Moreover, as noted in column 10, lines 5-11 and column 13, lines 16-29, the device can eject multiple markers individually in series. In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a marker delivery cannula and plunger in lieu of the marker delivery device of Fulton, III et al. to eject biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window, thus eliminating a procedural step and saving time.

The claims also differ from Fulton, III et al. in calling for a plurality of separate ultrasonically-detectable bodies and radiographically-detectable bodies with at least one marker body being ultrasonically detectable and at least one other marker body being radiographically detectable and the at least one of the radiographically-detectable bodies comprises a radiopaque element embedded therein having a closed loop that has at least one extension with a free end.

Delivering a plurality of detectable bodies via a cannula into a biopsy site (tube 54, column 4, lines 31-35), however, is known in the art. Foerster et al., for example, disclose in Figures 12-15 a cannula (tube 54) that is adapted to eject a plurality of biopsy markers (12b-12e) into a desired biopsy site via an ejector rod (column 10, lines 5-11). Foerster et al. also disclose the use of a gamma-shaped radiopaque element having a pair of extensions with free-ends to outwardly extend, thereby sufficiently to anchoring themselves to the target tissue (column 11, lines 27-32; see Figures 12-14). Such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enable secure implanting of an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Fulton, III et al. disclose, as noted above, a single marker being ultrasonically and radiographically detectable (column 3, lines 56-59). Fulton, III et al. also disclose that the change in the bioabsorbable element can occur via one of several ways (column 3, lines 45-50). Fulton, III et al. further disclose that the invention may employ one or more of these techniques or measures. For instance, *Fulton, III et al. disclose* *"the palpable marker may be inserted into the suspicious area of the breast under mammographic or ultrasonic guidance"* (column 2, lines 47-50; column 3, lines 15-18). The examiner respectfully disagrees that the radiographic detection and ultrasonic detection are only mutually exclusive. Fulton, III. et al. clearly disclose a single element that has mammographic or ultrasonic guidance functionality, thereby inherently having the ability to function with both radiographical and ultrasonic equipment. In addition, Fulton, III et al. explicitly disclose a single bioabsorbable element (34) that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced (column 3, lines 45-59). There is no disclosure that the single bioabsorbable element can only be enhanced by a single enhancement. Since Fulton, III et al. explicitly disclose that one or more techniques may be employed for measurement, and visual detectability, radiographic detectability, and ultrasonic detectability being separate measurements of the element, the bioabsorbable element may inherently employ both radiographic detectability and ultrasonic detectability. Furthermore, since Fulton, III et al. disclose a single bioabsorbable element having visual, radiographical and ultrasonic detectability and in view of the Foerster et al. teaching of a plurality of separate markers as well as the gamma shaped radiopaque marker, Fulton, III et al. in view of Foerster et al. would have a plurality of separate markers that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced "with at least one marker body which is ultrasonically detectable and at least one other marker body which is radiographically detectable by a radiopaque element embedded therein and having a closed loop that has at least one extension with a free end" given its broadest reasonable interpretation.

Furthermore, to the degree it can be argued that the combination does not teach a plurality of markers which has one which is ultrasonically detectable and another is radiographically detected, to provide a plurality of markers which has one which is ultrasonically detectable and another is radiographically detected would have been a mere engineering expediency as Fulton, III et al. clearly teach the use of a single marker being ultrasonically and radiographically detectable (column 3, lines 56-59) as well as a single bioabsorbable element (34) that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced (column 3, lines 13-18) and Foerster et al. teach the use of a plurality of separate markers being used for marking a biopsy site in a single application as well as the markers being various discernable shapes including a gamma shape.

With respect to the limitation of the plurality of separate preshaped solid bodies being collectively configured to at least partially fill the biopsy cavity site, Fulton, III et al. explicitly disclose the requirement and concern of the biopsy element (34) being placed within the biopsied open region (26) *and substantially filling the biopsied open region* (column 5, lines 3-21; column 6, lines 42-56). Foerster et al. is cited for the teaching, in Figures 12-15, of a cannula (tube 54; column 4, lines 31-35) that is adapted to eject a plurality of biopsy markers (12b-12e) to a desired biopsy site via an ejector rod (column 10, lines 5-11). In addition, Foerster et al. teach such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). Foerster et al. further teach a plurality of small beads (12i) of radiodense material could be deployed as marker elements in the biopsy cavity to serve as a guide during the extraction procedure and to denote the location of the previous biopsy for reference purposes (column 13, lines 16-29). Foerster et al. does not teach away from the use of the device or the plurality of separate preshaped solid bodies being collectively configured to at least partially fill the biopsy cavity site only a preference to use the device at multiple locations. Therefore since Fulton, III et al. explicitly teach the requirement and concern of the biopsy element (34) being placed within the biopsied open region (26) *and substantially filling the biopsied open region* and Foerster et al. teach the use of plurality of separate preshaped solid bodies within a cannula and delivery of such without reloading, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the filling substantially the entire biopsy region with one element of Fulton, III et al. with the plurality of elements of Foerster et al. as noted above.

Regarding claim 59, the cited prior art does not expressly disclose the body's ability to remain solid at 40º C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40º C in the previously described apparatus to ensure the marker remained intact after implantation.

With respect to the limitations of claim 59 and 62 and the radiopaque element having a closed loop that has at least one extension with a free end, Fulton, III et al.

disclose “the radiographic detectability of the element may be enhanced by a radiopaque marker”. Clearly Fulton, III. et al. disclose a separate object within the bioabsorbable element that provides a the radiographic detectability. With respect to the radiopaque member having a loop, Foerster et al. disclose the use of a gamma-shaped radiopaque element having a pair of extensions with free-ends to outwardly extend, thereby sufficiently to anchoring themselves to the target tissue (column 11, lines 27-32; see Figures 12-14) and after the bioabsorbable material the Fulton-Foerster marker has been absorbed by the body, the gamma-shaped radiopaque element of Foerster et al. would provide a means to sufficiently anchor itself, as noted above. Therefore, the Fulton, III et al. in view of Foerster et al. structure fully meets “a radiopaque member having a closed loop and at least one extension with a free end embedded therein” given its broadest reasonable interpretation.

16. Claims 66-75, 85-90, 92 and 95-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (U.S. Patent No. 6,270,464) in view of Foerster et al. (U.S. Patent No. 6,228,055) and further in view of Voegele et al. (U.S. Patent No. 6,261,302).

The Fulton-Foerster combination discloses all of the limitations, as previously set forth, except for calling for a ramp within the cannula inclined to a distal portion of the elongated discharge port and configured to urge a marker body into engagement with the ramp, up the ramp and out of the discharge port into the biopsy cavity.

However, a ramp within the cannula of a biopsy marker delivery tool configured to urge a marker body out of the discharge port into the biopsy cavity, as described by Voegele et al., is known in the art. Voegele et al. teach an applier (30) for delivering and deploying a biopsy marker to a biopsy site. In addition, Voegele et al.'302 further teach the applier (30) comprising an egress tube (63) having an egress opening (64) further having an egress ramp (65) (column 8, line 65 – column 9, line 2; see Figures 1, 2, 5, 7, 8, 13, 17, 18, 19)). Voegele et al. further teach the advantage of such a configuration provides for proper delivery and placement at the biopsy site (column 9, line 63 – column 10, line 4; see Figures 20-28). Furthermore it is noted that such a configuration provides that ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site. In view of Voegele et al., it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity to allow for proper delivery and placement at the biopsy site and to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity and to provide a mechanism to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

With respect to the limitations of claims 67, 73, 85, 86 and 99-101 and a plurality of markers being disposed in the inner lumen and the markers being of a certain material, Foerster et al., for example, disclose in Figures 12-15 a cannula (tube 54; column 4, lines 31-35) that is adapted to eject a plurality of biopsy markers (12b-12e) into a desired biopsy site via an ejector rod (column 10, lines 5-11). Foerster et al. also disclose the use of a gamma-shaped radiopaque element having a pair of extensions with free-ends to outwardly extend, thereby sufficiently to anchoring themselves to the target tissue (column 11, lines 27-32; see Figures 12-14). Such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). Foerster et al. further teach the detectable marker being preferably made in part of materials such as stainless steel, titanium, tantalum and nickel-titanium alloys (column 8, line 65 – column 9, line 2). As previously noted in the above rejection of claim 53 and in view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enable secure implanting of an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Regarding claims 68 and 89, Fulton, III et al. disclose the marker being formed of a bioabsorbable material (Abstract).

Regarding claim 69, the cited prior art does not expressly disclose the body's ability to remain solid at 40º C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40º C in the previously described apparatus to ensure the marker remained intact after implantation.

Regarding claim 70-72 and 88, Fulton, III et al. disclose the marker being ultrasonically detectable (column 3, lines 58-59), the marker having a colorant incorporated within (column 3, lines 54-56) and the marker being radiographically detectable (column 3, lines 59-58).

Regarding claims 90 and 92, Fulton, III et al. note in column 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material. Fulton, III. et al. further disclose the bioabsorbable material being dehydrated (Abstract; column 2, lines 28-29).4

Regarding claims 81-84 and 95-98 although the cited prior art does not disclose the specific Bloom rating of the body, the body of the cited prior art is nonetheless within the claimed Bloom rating range to achieve implantation (i.e., the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation).

17. Claims 76-84, 91, 93, 94 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (U.S. Patent No. 6,270,464) in view of Foerster et al. (U.S. Patent No. 6,228,055) and Voegele et al. (U.S. Patent No. 6,261,302) as applied

to claims 65-73, 85-90, 92 and 95-101 above, and further in view of Yamamoto (U.S. Patent No. 4,847,049), as evidenced by Ronan et al. (U.S. Patent No. 5,820,918).

The Fulton-Foerster-Voegele combination discloses all of the limitations, as previously set forth, except for calling for at least one of the bodies being formed of a cross-linked bioabsorbable material and having a radiographically detectable metallic ion bound to the cross-linked bioabsorbable material.

However, binding metallic ions to collagens in medical devices used in contact with bodily fluids and tissues is well known in the art to protect against bacterial and fungal attack. Yamamoto, for example, discloses contacting a renatured, cross-linked collagen with silver ion-containing solution with a PH from 4.0-9.0 to cause silver ions to be chelated to functional groups in the renatured collagen. The silver-chelated collagen is then exposed to UV radiation at a 210-310 nm wavelength for 5-15 minutes (column 4, lines 23-24) to strengthen the binding of the silver ions to the renatured collagen (column 2, lines 7-19 and 60-68). Yamamoto further teaches the use of renatured collagen instead of naturally occurring collagen to provide a collagen material that is less antigenic (column 1, lines 41-46). Ronan et al. teach that in addition to the silver ions having effective antiseptic characteristics, that the heavy metal of silver has inherent radiopaque characteristics. In view of Yamamoto, as evidenced by Ronan et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to bind a radiographically detectable metallic ion to the bioabsorbable material of Fulton, III et al. to cause silver ions to be chelated to functional groups in the collagen, thus further protecting against bacterial and fungal attack in addition to the inherent radiopaque characteristics of the silver ions.

Regarding claims 78 and 80, Fulton, III et al. note in column 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material. Fulton, III. et al. further disclose the bioabsorbable material being dehydrated (Abstract; column 2, lines 28-29).4

Regarding claims 81-84 although the cited prior art does not disclose the specific Bloom rating of the body, the body of the cited prior art is nonetheless within the claimed Bloom rating range to achieve implantation (i.e., the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation).

18. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302).

Foerster et al. disclose a delivery cannula with inner lumen and plunger to press against the marker bodies to discharge them from the cannula's discharge port (column 10, lines 5-12; see Figure 4-9, 12). Foerster et al. also discloses a discharge port (44) along a side of distal end of the cannula in communication with the plunger mechanism to deliver a marker bodies into the biopsy cavity. Foerster et al. further discloses the detectable marker bodies being preferably made in part of materials such as stainless steel, titanium, tantalum and nickel-titanium alloys (column 8, line 65 – column 9, line 2).

Foerster et al. discloses all of the limitations of the claimed invention, as previously set forth, except for calling for a ramp within the cannula inclined to a distal portion of the elongated discharge port and configured to urge a marker body out of the discharge port into the biopsy cavity.

However, a ramp within the cannula of a biopsy marker delivery tool configured to urge a marker body out of the discharge port into the biopsy cavity, as described by Voegele et al., is known in the art. Voegele et al. teach an applier (30) for delivering and deploying a biopsy marker to a biopsy site. In addition, Voegele et al.'302 further teach the applier (30) comprising an egress tube (63) having an egress opening (64) further having an egress ramp (65) (column 8, line 65 – column 9, line 2; see Figures 1, 2, 5, 7, 8, 13, 17, 18, 19)). Voegele et al. further teach the advantage of such a configuration provides for proper delivery and placement at the biopsy site (column 9, line 63 – column 10, line 4; see Figures 20-28). Furthermore it is noted that such a configuration provides that ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site. In view of Voegele et al., it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity to allow for proper delivery and placement at the biopsy site and to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity and to provide a mechanism to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

Remarks

19. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is the combination of Fulton, III et al. and Foerster et al. that meet the limitations of a plurality of markers which has one which is ultrasonically detectable and another being radiographically detected. Fulton, III et al. disclose, as noted above, a single marker being ultrasonically and radiographically detectable (column 3, lines 56-59). Fulton, III et al. also disclose that the change in the bioabsorbable element can occur via one of several ways (column 3, lines 45-50). Fulton, III et al. further disclose that the invention may employ one or more of these techniques or measures. For instance, *Fulton, III et al. disclose "the palpable marker may be inserted into the suspicious area of the breast under mammographic or ultrasonic guidance"* (column 2, lines 47-50; column 3, lines 15-18). The examiner respectfully disagrees that the radiographic detection and ultrasonic detection are only mutually exclusive. Fulton, III. et al. clearly disclose a single element that has mammographic or ultrasonic guidance functionality, thereby inherently having the ability to function with both radiographical and ultrasonic equipment. In addition, Fulton, III et al. explicitly disclose a single bioabsorbable element (34) that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced (column 3, lines 45-59). There is no disclosure that the single bioabsorbable element can only be enhanced by a single enhancement. Since Fulton, III et al. explicitly disclose that one or more techniques may be employed for measurement, and visual detectability, radiographic detectability, and ultrasonic detectability being separate measurements of the element, the bioabsorbable element may inherently employ both radiographic detectability and ultrasonic detectability. Furthermore, since Fulton, III et al. disclose a single bioabsorbable element having visual, radiographical and ultrasonic detectability and in view of the Foerster et al. teaching of a plurality of separate markers, Fulton, III et al. in view of Foerster et al. would have a plurality of separate markers that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced, thereby meeting" with at least one marker body which is ultrasonically detectable and at least one other marker body which is radiographically detectable" given its broadest reasonable interpretation. Therefore, it is deemed that Fulton, III et al. in view of Foerster et al. meets the recited limitation and would be obvious to combine.

20. With respect to applicant's argument that a skilled artisan would not know to select a body that remained solid at 40° C and that Fulton, III et al. teach against (or negate) such an obvious contention, the examiner respectfully disagrees. Fulton, III et al. disclose a bioabsorbable element being a dehydrated plug that may swell and a non-

swellable round pellet of PGA (column 2, lines 28-35) to be directly inserted into a biopsy cavity. It is important to note that it is known in the art that the interior body temperature is approximately 37° C. While Fulton, III et al. disclose the bioabsorbable material being made to absorb quickly to produce a local tissue inflammation (PGA pellet body selected to not remain solid at 40° C) (column 2, lines 35-39) and further that the bioabsorbable material can be a fluid or paste (column 7, lines 15-19), Fulton, III et al. explicitly disclose the bioabsorbable material after implant needing to be viewed after insertion and typically being absorbed within about a month (a collagen dehydrated plug selected to remain solid at 40° C) (column 2, lines 47-55). Since Fulton, III et al. disclose the bioabsorbable element remaining in the biopsy cavity for at least a month and it is known in the art that that the interior body temperature is approximately 37° C, the examiner maintains the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, the examiner further maintains it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40° C in the previously described apparatus to ensure the marker remained intact after implantation.

21. With respect to applicant's argument that Voegele et al. do not teach a ramp within the cannula inclined to a distal portion of the elongated discharge port and *configured to* urge a marker body into engagement with the ramp, up the ramp and out of the discharge port into the biopsy cavity, the examiner respectfully disagrees. While Voegele et al. is concerned with directing the biopsy device into a biopsy site, Voegele

et al. is equally concerned with deployment of a marker via the same tool (Title; Abstract; whole document). Voegele et al. explicitly teach a marker (31) being forced up a ramp (see Figures 21-28) that is configured to urge a marker body (31) into engagement with the ramp, up the ramp and out of the discharge port into the biopsy cavity. Therefore, the ramp of Voegele et al. fully meets “a ramp within the cannula inclined to a distal portion of the elongated discharge port and configured to urge a marker body into engagement with the ramp, up the ramp and out of the discharge port into the biopsy cavity" given its broadest reasonable interpretation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen J. Ralis whose telephone number is 571-272-6227. The examiner can normally be reached on Monday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Tu Hoang can be reached on 571-272-4780. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen J Ralis/
Examiner, Art Unit 3742

/TU B HOANG/
Supervisory Patent Examiner, Art Unit 3742

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SJR
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